IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION



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| ELIZABETH L. BRASHER, *et al.*, | ) | |
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| Plaintiffs, | ) | |
| | ) | |
| v. | ) | CV-98-TMP-2648-S |
| | ) | |
| SANDOZ PHARMACEUTICALS CORP., | ) | |
| | ) | |
| Defendant. | ) | |

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| RUBY QUINN, *et al.*, | ) | |
| | ) | |
| Plaintiffs, | ) | |
| | ) | |
| v. | ) | CV-98-TMP-2650-S |
| | ) | |
| SANDOZ PHARMACEUTICALS CORP., | ) | |
| | ) | |
| Defendant. | ) | |

**MEMORANDUM OPINION REGARDING**
**MOTIONS FOR PARTIAL SUMMARY JUDGMENT**

Before the court are the defendant's[1] motions for partial summary judgment on fraud and negligent misrepresentation and separate motions for partial summary judgment on warning claims,

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[1] Although identified in the style of the case as Sandoz Pharmaceuticals Corporation, the defendant has changed its name to Novartis Pharmaceuticals Corporation. The defendant will be referred to herein as "Sandoz."

all filed July 15, 1999.[2] The parties have filed extensive briefs and voluminous exhibits, as well as sending letters and other materials, dealing with the issues of (1) which state law applies to plaintiffs' tort claims,[3] (2) whether plaintiffs' tort claims are barred by the Supreme Court opinion in Buckman Company v. Plaintiffs' Legal Committee, 531 U.S. 341, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (Feb. 21, 2001); (3) whether Sandoz fraudulently misrepresented or concealed the potential hazards of Parlodel,[4] and (4) whether Sandoz adequately warned the plaintiffs of the potential hazards of Parlodel. After hearing the argument of counsel for both parties in the Globetti case, and having reviewed the briefs and evidence submitted in this case, including many supplemental filings by both parties, the court concludes that:

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[2] Similar motions were filed in a similar case before the undersigned magistrate judge, Globetti v. Sandoz Pharmaceuticals Corp., 98-TMP-2849-S. Those motions were denied by order dated February 2, 2001.

[3] The choice of law issue was addressed fully in the order denying summary judgment in Globetti, dated February 2, 2001. The reasons will not be restated fully herein, but the court will adopt that reasoning and will apply Alabama law to the plaintiffs' claims for the same reasons it applied Alabama law to Ms. Globetti's claims.

[4] Parlodel is the trade name for a drug produced by Sandoz which was, at the time plaintiffs gave birth, prescribed to suppress lactation.

1. Alabama law governs the plaintiffs' claims.

2. Buckman bars plaintiffs' claims based on fraudulent misrepresentation allegedly made by Sandoz to the Food and Drug Administration ("FDA").

3. Plaintiff Brasher has set forth sufficient evidence to create a genuine issue of material fact as to her remaining fraud claims; but Plaintiff Quinn has not come forward with sufficient evidence to overcome defendant's motion on the fraud claims.

4. Plaintiff Brasher has set forth sufficient evidence to create a genuine issue of material fact as to defendant's failure to warn, but plaintiff Quinn has not come forward with sufficient evidence to overcome defendant's motion on the warning claim.

5. As to plaintiffs' claims asserting strict liability, the defendant correctly notes that Alabama law does not provide such remedy.

Consequently, defendant's motions for partial summary judgment on the issues of (1) plaintiff Brasher's fraud and/or negligent misrepresentation directed to plaintiff and her doctors, and (2) plaintiff Brasher's failure-to-warn claims are due to be denied. Defendant's motions as to (1) plaintiff Quinn's fraud, suppression, and negligent misrepresentation claims; (2) plaintiff Quinn's failure-to-warn claims; (2) both plaintiffs' fraud-on-the-FDA claims; and (3) both plaintiffs' claims asserting strict liability are due to be granted.

## I. UNDISPUTED FACTS

Sandoz is a pharmaceuticals company that produced Parlodel, a prescription drug manufactured and sold in the United States and other countries. Sandoz produces the drug in New Jersey, where its headquarters are located. Chemically, Parlodel is bromocriptine mesylate, an ergot alkaloid with an added bromine atom.

### A. The Marketing Of Parlodel

Beginning in 1978, Parlodel was marketed in the United States for the treatment of amenorrhea (the absence of menses) and galactorrhea (spontaneous lactation). Parlodel was approved by the Food and Drug Administration ("FDA") for prevention of physiological lactation ("PPL") from 1980 until January of 1995. Beginning in 1980, Sandoz began to aggressively market Parlodel to obstetricians for routine PPL use. Sandoz specifically aimed to get Parlodel placed on the standing orders of obstetricians, noting that it would then be prescribed for all non-breastfeeding postpartum patients. Its marketing included solicitations to doctors through advertisements and through personal sales calls made by the drug sales representatives.

Even before the drug was marketed in the United States, Sandoz-Basle (apparently an affiliated or parent company located in Switzerland) had collected reports of serious adverse drug reactions ("ADRs") connected to Parlodel. Included in the list of ADRs were "vasospastic reactions." No later than April of 1984, Sandoz had received "a sufficient number" of reports of seizures in patients given Parlodel for PPL to opine that there may be a "true association" between the drug and seizures. Sandoz recognized, years before the drug was approved for PPL use, that Parlodel could cause both vasodilation (the dilation of blood vessels) and vasoconstriction (the constriction of blood vessels). In spite of this knowledge, Sandoz took the position publically that Parolodel could cause hypotension, but not hypertension. Vasoconstriction, when it occurs in the brain, can cause a stroke. When it occurs in the heart, it can cause a heart attack, more specifically known as a myocardial infarction ("MI").[5]

After the FDA received numerous reports of seizures in patients given Parlodel for PPL, and after Sandoz had admitted that the seizure cases "were probably related to episodes of hypertension, which we know can occur under Parlodel," the FDA

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[5] The plaintiffs have offered expert testimony to support their conclusion that vasospasm, which is commonly known as ergotism, can cause both strokes and MIs.

requested that Sandoz include reports of hypertension, "convulsive activity," and stroke under the "Adverse Reactions" section of its package insert. Although Sandoz had admitted internally that Parlodel could cause hypertension and seizures, it opposed inclusion of the reports as adverse reactions, and took the position with the FDA that such events were not caused by Parlodel.

The FDA in 1983 advised Sandoz that, pursuant to 21 C.F.R. 201.5(e), the package insert should be revised to include new warnings "as soon as there is reasonable evidence of an association of a serious hazard," even when causation has not been proven. The FDA also requested a revision of Parlodel's package insert to reflect a more serious warning. Sandoz included the revised warnings beginning in March of 1984, and continued to aggressively market Parlodel, instructing its sales force to "[b]e sure that Parlodel usage is not discontinued due to adverse experiences," and to "convert users of estrogen and non-treaters of PPL to Parlodel therapy." While internally reporting that there "may be a true association" between Parlodel use and hypertension, seizures, or stroke in postpartum women taking Parlodel for lactation suppression, the sales force was told that such adverse events were not "necessarily related" to Parlodel, and were told that hypertension has "never before" been linked to Parlodel. On at

least one occasion in 1984, the FDA deemed Sandoz's advertisements in the "Obstetrics and Gynecology" journal, ads directed toward the physicians who prescribe Parlodel, to contain at least three false statements, and to be generally "false and/or misleading."

The FDA in 1985 requested that certain "contraindications" be added to the Parlodel package insert to inform physicians that the drug was not approved for use in certain situations, *i.e.*, when a patient has suffered from hypertension or toxemia during pregnancy, or has received other ergot alkaloid drugs after delivery.[6] In spite of the FDA request, Sandoz continued to market Parlodel for routine use, seeking to "preserve" and "expand" the PPL business. Sandoz sales representatives were instructed to continue to push doctors to include Parlodel on their standing orders, providing medication order cards for use in hospitals that would order Parlodel for "all" non-breastfeeding patients.

Throughout the 1980s, Sandoz and the FDA continued to receive reports of adverse experiences, including hypertension, cardiac arrest, and stroke. In 1981, Sandoz completed a study, required by the FDA, known as "Study 60." In Study 60, Sandoz researchers concluded that hypertension could be caused by Parlodel, but Sandoz

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[6] Apparently, other ergots produced by Sandoz, methergine and caffergot, were commonly used during delivery to prevent hemorrhaging.

never submitted Study 60 to the FDA, despite repeated requests, until after Parlodel was withdrawn from the PPL market almost 15 years after the study was completed. In the late 1980s, the FDA persisted in its efforts to get Sandoz to revise its package insert and to send "Dear Doctor" letters[7] advising of the revisions. Apparently, in spite of Sandoz's alleged multiple mailings, a majority of the practicing obstetricians to whom the letters were aimed never received them.

Reports of other serious adverse reactions continued to be received by Sandoz in 1987 concerning stroke and postpartum myocardial infarctions. In 1988, an FDA advisory committee recommended that Parlodel not be used "routinely," but be limited to women with "specific indications," such as those who deliver stillborns. Even so, Sandoz continued to market Parlodel aggressively for PPL and did nothing to advise doctors who had Parlodel on standing order to change their routine use of the drug.

In 1989, the FDA requested that Sandoz voluntarily withdraw Parlodel from the market for PPL use. Sandoz declined, and continued to promote the sale of Parlodel, stressing both the

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[7] Such mass mailings are a common method by which pharmaceuticals companies provide information directly to the prescribing physicians in order to draw their attention to any labeling updates or changes in the product.

"safety" and "efficacy" of Parlodel in spite of its own studies that demonstrated a "substantial positive association" between Parlodel and seizures and "an extremely strong positive association" between Parlodel and seizures in women who had received other ergots after delivery.

In 1994, the FDA notified Sandoz that it would hold a hearing on the withdrawal of Parlodel for prevention of postpartum lactation. Sandoz continued to maintain publicly that Parlodel was "safe." On January 17, 1995, the FDA withdrew Parlodel from the market for inhibiting postpartum lactation.

During the time Parlodel was prescribed routinely for postpartum lactation suppression, Sandoz, in accordance with federal regulations, distributed the drug with a package insert that contained information about the drug. The language in that package insert was approved by the FDA. The language of the package insert in effect at the time the drug was prescribed to plaintiffs Elizabeth Brasher and Ruby Quinn, which also was published in the Physician's Desk Reference, states:

**WARNINGS**

> **Fifteen cases of stroke during Parlodel (bromocriptine mesylate) therapy have been reported mostly in postpartum patients whose prenatal and obstetric courses has been uncomplicated. Many of these patients experiencing seizures and/or strokes reported developing a constant**

**and often progressively severe headache hours to days prior to the acute event. Some cases of strokes and seizures during therapy with Parlodel (bromocriptine mesylate) were also preceded by visual disturbances (blurred vision, and transient cortical blindness). Four cases of acute myocardial infarction have been reported, including 3 cases receiving Parlodel (bromocriptine mesylate) for the prevention of physiological lactation. The relationship of these adverse reactions to Parlodel (bromocriptine mesylate) administration is not certain.**

**...**

**ADVERSE REACTIONS**

**...**

**Physiological Lactation**

**...Serious adverse reactions include 38 cases of seizures (including 4 cases of status epilepticus), 15 cases of stroke, and 3 cases of myocardial infarction among postpartum patients. Seizure cases were not necessarily accompanied by the development of hypertension. An unremitting and often progressively severe headache, sometimes accompanied by visual disturbance, often preceded by hours to days many cases of seizure and/or stroke. Most patients had shown no evidence of toxemia during the pregnancy.**

The package insert underreported the number of strokes and seizures that had been reported to be caused by Parlodel. By 1995, Sandoz had received more than 30 reports of Parlodel-linked strokes in women who were taking the drug for PPL. Similarly, Sandoz reported 4 incidents of heart attack or MI, but had received reports of 15. The package insert did not refer to any deaths, although Sandoz had apparently received reports of approximately 20 deaths in relation to the ingestion of Parlodel.

B. Ruby Quinn

Plaintiff Ruby Quinn[8] delivered a child by Caesarean section on August 25, 1993. She initially chose to breastfeed her baby. On August 31, 1993, Ms. Quinn returned to the hospital, complaining of stomach pains. While in the hospital, she decided to stop breastfeeding. She was given a prescription for Parlodel on or about September 1, 1993. The Parlodel was prescribed to be taken twice a day for 10 days, although it is not clear whether Mrs. Quinn took the Parlodel as prescribed, or by using only one tablet per day for 20 days.[9]

On or about September 14, 1993, Ms. Quinn developed headaches, which she attributed to dental problems. Her dentists prescribed Tetracycline, Amoxil, and a pain medication. On September 21,

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[8] Plaintiff now goes by the name Ruby Quinn Hatcher, but will be referred to herein as Ms. Quinn.

[9] Ms. Quinn has testified that she was not given any instructions as to the use of the Parlodel and that she took only one per day. However, she told one doctor that she was "not sure" how she took the Parlodel. Ms. Quinn has testified that she "believes" she took one pill per day in the mornings. In any event, plaintiff has offered evidence from Dr. Coyle that Parlodel can be detected even several days after ingestion, and that the drug "seems to have a very prolonged bioactive half-life and its effects linger[] for a significant length of time." Transcript of 6/5/01 hearing, at p. 45. From this testimony, a jury could infer that the Parlodel caused Ms. Quinn's stroke even if she had stopped taking the drug three or four days before the stroke.

1993, the plaintiff developed paralysis on her left side and experienced slurred speech. Emergency medical workers recorded her blood pressure as 180/90. She was taken to the hospital, where her blood pressure was recorded as 180/84. An MRI was done, revealing a recent cerebral infarction in the right lenticular nuclear and periventricular region. Other tests showed an occlusion of the right middle cerebral artery. A cerebral angiogram taken September 27, 1993, showed an abrupt occlusion of the right middle cerebral artery. In layman's terms, Mrs. Quinn had suffered a stroke.

Dr. Samuel Gray prescribed Parlodel to Ms. Quinn. He has testified that he had read the package insert, as published in the PDR, before prescribing the drug. He routinely prescribed Parlodel for non-breastfeeding mothers and had Parlodel on his standing orders at the hospitals where he delivered babies. Dr. Gray does not recall receiving either of Sandoz's "Dear Doctor" letters sent in 1987 and 1988.[10] Dr. Gray has testified that he does not recall any meetings with any Sandoz sales representatives, and does not

[10] He was a resident at that time and not a member of ACOG. Accordingly, there is no evidence that he would have been a doctor on the mailing list used by Sandoz for the distribution of the letters.

believe he was ever misled or confused by any Sandoz advertisement or literature relating to Parlodel.

C. Elizabeth Brasher

Plaintiff Elizabeth Brasher delivered a child on February 15, 1994. On the following day, she underwent a tubal ligation. She chose not to breastfeed her baby, and was given a prescription for Parlodel on or about February 15, 1994, by her obstetrician, Dr. Jerry Gurley. The Parlodel was prescribed to be taken twice a day for 10 or 14 days. She had previously taken Parlodel in 1991 after a pregnancy, and experienced no known adverse reaction.

On or about February 21, 1994, Ms. Brasher experienced left-sided paralysis and was taken to the emergency room. It was determined that Ms. Brasher had suffered a cerebral infarction in the right temporal region. An arteriogram in March of 1994 showed the appearance of fibromuscular displasia ("FMD") in the left common carotid artery.[11]

Dr. Gurley prescribed Parlodel routinely for non-breastfeeding women. The drug was on his standing orders at the hospital where

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[11] The parties dispute whether Ms. Brasher had FMD, or whether the radiographic picture appeared similar to FMD because of the use of ergot alkaloids. Defendant takes the position that Ms. Brasher had FMD, but defendant's expert Dr. Bucholz admits that FMD and vasospasm can be confused on agiography.

Ms. Brasher gave birth. Prior to prescribing Parlodel to Ms. Brasher, Dr. Gurley was not aware that the FDA had determined that Parlodel should not be used "routinely," nor was he aware of the number of strokes that occurred in postpartum women using Parlodel. Dr. Gurley does not recall ever receiving or seeing copies of the two "Dear Doctor" letters that Sandoz claims it sent advising him of a change in the package insert. He states that he would have read the letter if he had received it.

Sandoz admits that from the time the package insert was developed in 1987 until after Ms. Brasher received Parlodel, the number of "adverse events" listed in the package insert and PDR was not changed, even though Sandoz received more reports of adverse events, including reports of stroke. Dr. Gurley testified that the language of the package insert led him to believe that the 15 cases of stroke reported in the package insert "were probably not related to Parlodel and that Parlodel was safe to prescribe" to his patients. He assumed that the numbers of adverse events listed in the package insert were accurate and current. Furthermore, Dr. Gurley has testified that if Sandoz had informed him of the risks of Parlodel by disclosing the accurate numbers of adverse events and by revealing that Sandoz had conducted an epidemiology study that found a positive association between Parlodel and stroke or

seizure, he would not have prescribed the drug to Ms. Brasher. Dr. Gurley also has stated that if he had known that the FDA asked Sandoz to withdraw Parlodel from the market for the PPL indication in 1989 he would have made further inquiries about the FDA's concerns. Although Dr. Gurley does not recall any specific visits with Sandoz's drug sales representative, Bo Trammel, he recalls that Mr. Trammel called on him repeatedly, in one-to-two-month intervals.

D. Parties' Positions

The defendant argues in support of its motions for partial summary judgment that, in the absence of testimony establishing a misrepresentation by Sandoz to each plaintiff, the plaintiff's cause of action for fraud under Alabama law fails, and defendant is entitled to entry of summary judgment in its favor. Defendant further argues that the plaintiffs' failure-to-warn claims also are due to be dismissed because the defendant discharged its duty to warn by providing the package insert information, and because the decision to take Parlodel was not made by the plaintiffs, but by a "learned intermediary": Dr. Gurley in the case of Ms. Brasher, and Dr. Gray in the case of Ms. Quinn. In addition, defendant asserts that, pursuant to the Supreme Court's decision in Buckman Company

v. Plaintiffs' Legal Committee, 531 U.S. 341, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001), the plaintiffs' fraud claims premised on any misrepresentations allegedly made to the FDA are not actionable.

The plaintiffs counter that a fraud claim is viable even absent a direct representation to the plaintiffs, and that Sandoz is liable for failing to adequately warn the plaintiff of the hazards related to the use of Parlodel to inhibit postpartum lactation. Plaintiffs further argue that Buckman precludes only claims that are premised solely on a "fraud-on-the-FDA" theory, and not claims premised on fraud or suppression that ultimately reached the doctors who prescribed the drug to the plaintiffs.

## II. SUMMARY JUDGMENT STANDARD

Under Federal Rule of Civil Procedure 56(c), summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). The party seeking summary judgment "always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers

to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986)(quoting Fed. R. Civ. P. 56(c)). The movant can meet this burden by presenting evidence showing there is no dispute of material fact, or by showing that the nonmoving party has failed to present evidence in support of some element of its case on which it bears the ultimate burden of proof. Celotex, 477 U.S. at 322-23. There is no requirement, however, "that the moving party support its motion with affidavits or other similar materials *negating* the opponent's claim." Id. at 323.

Once the moving party has met his burden, Rule 56(e) "requires the nonmoving party to go beyond the pleadings and by her own affidavits, or by the 'depositions, answers to interrogatories, and admissions of file,' designate 'specific facts showing that there is a genuine issue for trial.'" Id. at 324 (quoting Fed. R. Civ. P. 56(e)). When the nonmoving party does not respond, "summary judgment, if appropriate, shall be entered against the adverse party." Fed. R. Civ. P. 56(e).

The nonmoving party may not merely rest on her pleadings. Celotex, 477 U.S. at 324. "[T]he plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for

discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Id. at 322.

After the plaintiff has had the opportunity to respond to a proper motion for summary judgment, the court must grant the motion if there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The substantive law will identify which facts are material and which are irrelevant. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Id. at 248. "[T]he judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Id. at 249. His guide is the same standard necessary to direct a verdict: "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Id. at 251-52; see also Bill Johnson's Restaurants, Inc. v. N.L.R.B., 461 U.S. 731, 745 n.11 (1983). However, the nonmoving party "must do more than show that there is some metaphysical doubt as to the material facts.

"Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted. Anderson, 477 U.S. at 249 (citations omitted); accord Spence v. Zimmerman, 873 F.2d 256 (11th Cir. 1989). Furthermore, the court must "view the evidence presented through the prism of the substantive evidentiary burden," so there must be sufficient evidence on which the jury could reasonably find for the plaintiff. Anderson, 477 U.S. at 254; Cottle v. Storer Communication, Inc., 849 F.2d 570, 575 (11th Cir. 1988). Nevertheless, credibility determinations, the weighing of evidence, and the drawing of inferences from the facts are the function of the jury, and therefore the evidence of the non-movant is to be believed and all justifiable inferences are to be drawn in his favor. Anderson, 477 U.S. at 255. The non-movant need not be given the benefit of every inference but only of every reasonable inference. Brown v. City of Clewiston, 848 F.2d 1534, 1540 n.12 (11th Cir. 1988).

## III. FRAUD

The defendant seeks summary judgment on all of plaintiffs' claims based on fraud.[12] In its renewed motion for summary judgment, defendant asserts that all the plaintiffs' fraud claims are barred by Buckman. Defendant further asserts that it is entitled to summary judgment in its favor on the basis that plaintiffs have failed to come forward with evidence sufficient to withstand summary judgment on the issue of whether: (1) Sandoz made any false representations or suppressions of material fact to plaintiffs, their doctors, or the public; (2) any alleged misrepresentation or concealment induced plaintiffs to take, or the doctors to prescribe, Parlodel; and (3) the alleged fraud caused the injuries.

### A. Buckman

At the heart of defendant's renewed motion for partial summary judgment on plaintiffs' fraud, suppression, and negligent misrepresentation claims is the assertion that the Buckman decision precludes any claim, and indeed any evidence, relating to

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[12] Plaintiffs assert claims for fraud, negligent misrepresentation, and suppression, all of which are viable claims under Alabama law. See Alabama Code §§ 6-5-100 through 104. The fraud claims will be treated jointly herein.

defendant's communications with the FDA and any other communications "controlled" by the FDA. Defendant argues that, not only are plaintiff's fraud-on-the-FDA claims now barred, but also virtually all of plaintiff's other claims relating to fraud on the medical community and the adequacy of the warnings contained in the FDA-approved package insert are barred. These claims, Sandoz contends, are preempted by Buckman because all are grounded on communications between the defendant and the FDA or approved and controlled by the FDA.

While the court agrees that Buckman expressly preempts fraud-on-the-FDA claims, it is unpersuaded that the rest of plaintiff's claims of misrepresentation, suppression, negligence, and inadequate warning are preempted. First, it appears that the *only* claim set forth in Buckman, and therefore the only claim considered by the Supreme Court, was that certain information had been misrepresented to the FDA, thereby causing the FDA to find that the medical device at issue was a "substantial equivalent" of a predicate device. There is nothing in Buckman to suggest that the plaintiffs in that case alleged other grounds for relief, such as fraud on the medical community or that the product was defective and unreasonably dangerous. The exclusive focus of the Supreme

Court's analysis is on the "fraud-on-the-agency" theory and its unavoidable conflict with the agency's own enforcement schemes.

Second, Buckman must be read against the backdrop of Medtronics, Inc. v. Lohr, 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed. 2d 700 (1996), and Silkwood v. Kerr-McGee Corporation, 464 U.S. 238, 104 S.Ct. 615, 78 L.Ed. 2d 443 (1984). While it is true that Buckman is based on implied or conflict preemption and Lohr is grounded on express preemption, Silkwood also is an implied preemption case. In Buckman the Supreme Court distinguished (rather than overruled) Silkwood on the very basis discussed in the preceding paragraph, that is, that Silkwood involved state-law claims beyond simply a "fraud-on-the-agency" theory. Read together, these cases make clear that the only theory preempted is that resting exclusively on the fact that the federal agency was itself the victim of the fraud. Although Buckman precludes a plaintiff from seeking damages because the defendant lied to the FDA, it is something completely different to contend that plaintiff is precluded from seeking damages for injuries due to lies made to her. Notwithstanding that information may have been misrepresented to or concealed from the FDA, once defendant undertook to misrepresent those facts *to plaintiff*, or to conceal *from plaintiff* facts it was bound to disclose, the plaintiff's claim no longer

rests simply on the assertion that the agency was defrauded but on the additional fact that *she* was defrauded.

The court also is convinced that Buckman does not preclude plaintiff's inadequate warning claims, even though the warning itself – the package insert – was approved by the FDA. Aside from whether the FDA approved the package insert based on misrepresented or suppressed information, plaintiff asserts simply that the warning was not reasonably adequate to alert physicians and their patients to risks associated with prescribing Parlodel for one of its intended purposes, the suppression of postpartum lactation. The duty ran to the consumer, not just to the FDA. As the Supreme Court emphasized in Buckman, the claim there was grounded entirely on the duty of disclosure to the FDA, not any separate duty owed to the plaintiff. Indeed, the Court distinguished Medtronics by pointing out that the earlier case rested on "the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of the FDCA requirements." In the case before the court, plaintiff's claims also do not arise "solely from the violation of the FDCA requirements." Defendant owed separate duties beyond simply full and fair disclosure to the FDA, duties not to market a defective and unreasonably dangerous product, not to misrepresent or suppress the facts needed by

*physicians and consumers* to assess the safety of the product and to adequately warn of known risks associated with it. These duties existed irrespective of the FDCA. Thus, while a plaintiff cannot recover simply because defendant defrauded a federal agency, nothing in Buckman suggests that she cannot recover where the misrepresentations or suppression were directed *at her* (through her physician) or when the warning given (even though FDA approved) inadequately disclosed the hazards of the product.[13]

The defendant's reliance on Irving v. Mazda Motor Corp., 136 F.3d 764 (11th Cir. 1998), and James v. Mazda Motor Corp., 222 F.3d 1323 (11th Cir. 2000), is misplaced. The Eleventh Circuit Court of Appeals expressly distinguished Irving in Goodlin v. Medtronics, Inc., 167 F.3d 1367 (11th Cir. 1999), finding defendant's argument for implied preemption based on Irving "meritless." Id. at n. 5.

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[13] This case may be a good example of why the duty to warn is not limited to what the FDA has approved. Plaintiffs contend that the FDA tried several times to get defendant to update the warning in the package insert, but defendant refused. To argue that once the FDA approves a package insert the defendant has no further duty to give an adequate warning creates an incentive for pharmaceutical companies to oppose all efforts by the FDA to secure clearer package inserts. If that were the case, drug manufacturers could avoid liability simply by resting on the formerly approved package insert (regardless of how long ago the approval occurred and how much information about the drug had changed) and resist all efforts to change it. The FDA approval of the package insert becomes a complete bar to liability, regardless of how inadequate it may have become over time.

Interestingly, the panel that decided Goodlin included Judges Edmondson and Tjoflat, who authored Irving and James, respectively. The holding in Goodlin that the assertion of implied or conflict preemption in the context of a medical device (a pacemaker lead) is certainly more instructive for this case than Irving and James, which were decided under the National Traffic and Motor Vehicle Safety Act of 1966 and the Federal Motor Vehicle Safety Standards. The Goodlin court clearly rejected implied preemption with respect to common-law claims arising from medical devices, notwithstanding the FDCA and the MDA. See also, Brooks v. Howmedica, Inc., 236 F.3d 956 (8th Cir. 2001).

Accordingly, the motions for partial summary judgment on plaintiffs' fraud-on-the-FDA claims are due to be granted.

B. Fraud Directed Toward Plaintiffs

To survive summary judgment on the active fraud claims, plaintiffs must show that the defendant made "(1) a false representation, (2) of an existing material fact, (3) that is reasonably relied upon, and (4) damage resulting as a proximate cause." Wheelan v. Sessions, 50 F. Supp. 2d 1168, 1172 (M.D. Ala. 1999). To survive summary judgment on the concealment claims, the plaintiffs must demonstrate that the defendant suppressed a

material fact, having had a duty to communicate that fact, and that the injury resulted from the suppression. Doss v. Serra Chevrolet Inc., 781 So. 2d 983 (Ala. Civ. App. 2000).

1. The Plaintiffs' Standing To Sue

The defendant first asserts, and the plaintiffs agree, that no misrepresentation was made to the plaintiffs. While it is generally true that a third party to a misrepresentation has no cause of action for fraud, the Alabama Supreme Court has recognized that "it is not always necessary to prove that a misrepresentation was made directly to the person who claims to have been injured." Wheelan, 50 F. Supp. at 1174, quoting Thomas v. Halstead, 605 So. 2d 1181, 1184 (Ala. 1992). In spite of the general rule that a stranger to a transaction has no cause of action for fraud, there is an exception. "[I]f a third person is injured by the deceit, he may recover against the one who made possible the damages to him by practicing the deceit in the first place." Wheelan, 50 F. Supp. 2d at 1174, quoting 37 C.J.S. Fraud § 60 at 344. It then follows that there exists a duty "not to make a false representation to those to whom a defendant intends, for his own purposes, to reach and influence by the representation." Wheelan, 50 F. Supp. 2d at 1174,

quoting Colonial Bank of Ala. v. Ridley & Schweigert, 551 So. 2d 390, 396 (Ala. 1989).

In the instant case, the fraudulent representations that plaintiffs allege were made not to the plaintiffs but to the treating doctors. The parties injured by this alleged deceit, however, clearly are Ms. Quinn and Ms. Brasher. Furthermore, it is clear that Sandoz, for its own purposes of promoting its product and making a profit, intended to reach and influence the patients of obstetricians, such as the plaintiffs. Sandoz wanted to promote its product as safe and effective so that obstetricians would prescribe the drug to their patients. Consequently, the court finds that each plaintiff has a cause of action for the alleged fraud, even absent any direct representations by Sandoz to either plaintiff.

2. Falsity

To be actionable as active fraud, the representations made by Sandoz in the package insert or the sales pitches to doctors, (or both), must be shown to be false. In this case, the defendant admits that the package insert at issue asserted that 15 cases of stroke had been reported in which the patient had received Parlodel for suppression of postpartum lactation. The plantiffs have

produced evidence which, if believed, would indicate that the defendant knew of many more such events. The defendant admits that its Parlodel package insert also states that: "The relationship of these adverse reactions to Parlodel (bromocriptine mesylate) administration is not certain." The plaintiffs have produced evidence from which a reasonable jury could infer that Sandoz knew of a causal relationship between its drug and vasoconstrictive reactions such as ischemic stroke. The plaintiffs also have produced evidence that, even after the FDA instructed the defendant that Parlodel should not be used in routine cases of postpartum lactation suppression, the defendant continued to market the drug to doctors as a drug that should be placed on standing order. Construing the facts of the instant case in the light most favorable to the plaintiffs, the court concludes that a reasonable jury could find that representations made by the defendant to Drs. Gurley and Gray, through the package insert or PDR, about the

safety of Parlodel[14] could be found to be false. Accordingly, the first element of active fraud is met.

3. Concealment

To be actionable as concealment, the plaintiffs must demonstrate that the defendant suppressed a material fact that it had a duty to disclose. Evidence relating to this element goes hand in hand with the evidence of falsity. Plaintiffs have set forth evidence to support their claim that the number of strokes reported on the package insert and to the FDA were false, and also that Sandoz knew of other cases and suppressed them. Similarly, the plaintiffs have produced evidence from which a jury could

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[14] The defendant further argues that the facts allegedly misrepresented were not material. The court rejects this argument as to plaintiff Brasher in light of Dr. Gurley's testimony that he felt the number of adverse events reported in the package insert and the warning language used indicated a lack of causation and "reassured [him] that these adverse events were probably not related to Parlodel and that Parlodel was safe to prescribe to [his] patients." Affidavit of Gurley, Pl. Ex. B1. Consequently, it is reasonable to expect that the reporting of a higher number of adverse events and/or different language regarding the relationship between the events and Parlodel might have led Dr. Gurley to question whether Parlodel caused strokes in postpartum women and might have alerted him to the need to remove Parlodel from his standing order. As to Ms. Quinn, there is no evidence before the court that the information was material to Dr. Gray. As set forth under the discussion of the element of reliance in section III B 4, Ms. Quinn's fraud claims are due to be dismissed.

conclude that Sandoz suppressed its own conclusions about the hazards of Parlodel, for example, by failing to disclose Study 60 to the FDA. Accordingly, the court finds that the plaintiffs have met their burden of showing that the defendant concealed material facts about the safety of Parlodel.

The question of whether Sandoz had a duty to disclose such information is an even simpler one. Under Alabama law, the failure to tell the whole truth, or to provide only partially correct information, may constitute fraudulent concealment. See Cunningham v. H.A.S. Inc., 74 F. Supp. 2d 1157, 1162 n.6 (M.D. Ala. 1999). In fact, Alabama courts have held that:

> To tell half a truth has been declared to be equivalent to the concealment of the other half. A partial and fragmentary disclosure, accompanied by the willful concealment of material and qualifying facts is not a true statement, and is as much a fraud as an actual misrepresentation, which, in effect, it is. Therefore, if one willfully conceals and suppresses such facts, and thereby leads the other party to believe that the matters to which the statements made relate are different from what they actually are, he is guilty of a fraudulent concealment.

Gold Kist, Inc. v. Brown, 495 So. 2d 540 (Ala. 1986), quoting Jackson Co. v. Faulkner, 315 So. 2d 591 (Ala. Civ. App. 1975). Furthermore, it has been noted that even though one may not have a duty to disclose certain facts, if he "undertakes to do so, either

voluntarily or in response to inquiries, he is bound not only to state truly what he tells, but also not to suppress or conceal any facts within his knowledge which will materially qualify those stated." Jackson, 315 So. 2d at 600. Accordingly, in this case, a duty arose when Sandoz undertook to disclose information about the safety of Parlodel.

The existence of a duty may arise in other ways, as well. Alabama law requires an assessment of a number of factors, including: (1) the relationship among the parties; (2) the relative knowledge of the parties; (3) the value of a particular fact; (4) the customs of the trade; and (5) other relevant circumstances. Cunningham, 74 F. Supp. 2d at 1163. In this case, Sandoz had a duty under federal law to disclose certain reports of adverse reactions to the FDA and, thereby, to doctors and patients.[15] Sandoz's level of knowledge as to the effects of Parlodel clearly was superior to either that of the FDA or any individual doctor. The value of the fact that Parlodel might cause stroke was clearly paramount under circumstances such as plaintiffs', where both women had no medical need for the drug, but took it solely for PPL.

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[15] The plaintiffs have not addressed directly the "customs" of the pharmaceuticals industry, but the evidence submitted regarding FDA regulations makes clear that pharmaceuticals companies customarily (and by law) disclose information about the safety of their products to the FDA.

Consequently, Sandoz had a duty to disclose to doctors information about the safety of Parlodel. As discussed in Section III B 3 *supra*, a reasonable juror could conclude that, in reporting 15 incidents of stroke in the package insert, Sandoz concealed the other 17 strokes that it knew had occurred. Finally, the "relevant circumstances" of this case weigh in favor of finding that Sandoz had a duty to disclose the true hazards of Parlodel. Sandoz knew of, and had promoted, the routine use of Parlodel in postpartum women even after the FDA rejected such use and even knowing that doctors were not monitoring the blood pressure of these women after they were discharged from the hospital. Considering all of the factors and "relevant circumstances" as required by Alabama law, the court finds that Sandoz had a duty to disclose to prescribing doctors the known hazards of ingesting its drug, and that it failed to do so.

4. Reasonable Reliance

The defendant argues that the plaintiffs must have "justifiably relied" upon the alleged misrepresentations. (Defendant's brief, p. 23). The law in Alabama, however, now requires a lesser standard of reliance, deemed "reasonable reliance." See Foremost Ins. Co. v. Parham, 693 So. 2d 409, 423

(Ala. 1997)(adopting reasonable reliance standard and rejecting the justifiable reliance standard set forth in prior cases). Under the applicable standard, the reliance need only have been "reasonable under the circumstances." Wheelan, 50 F. Supp. 2d at 1173. In this case, Dr. Gurley asserted that he met with Sandoz's sales representative Bo Trammel on several occasions, and that he read the information in the PDR at some time before prescribing Parlodel for Ms. Brasher. He further testified that he relied upon the information provided by Sandoz to be complete and accurate, and that, had he known of the risks of Parlodel known to Sandoz, he would not have prescribed it to Ms. Brasher. Certainly, defendant cannot argue that it is unreasonable for a doctor to rely on the PDR in making prescribing decisions.[16] Plaintiff Brasher, in turn, clearly relied upon Dr. Gurley in taking the Parlodel that was prescribed. Her action in taking the drug as prescribed cannot be deemed less than reasonable. Consequently, plaintiff Brasher has met her burden of showing the second element of fraud.[17]

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[16] If Dr. Gurley's reliance on the PDR was "unreasonable," then Ms. Brasher - like most every patient who has ever received a prescription from a doctor - would have a cause of action for medical malpractice, and doctors would be required to conduct their own research into a drug before being able to prescribe it.

[17] Defendant has asserted that Alabama has rejected a "fraud on the market" theory, citing, *i.e.*, Ex parte Household Retail Services, Inc., 744 So. 2d 871 (Ala. 1999). In that case,

In the case of Ms. Quinn, however, the evidence is not so clear. Dr. Gray has testified that he was familiar with the package insert, as it appeared in the PDR, for Parlodel at the time he prescribed it to Ms. Quinn in 1993. There is no evidence that Dr. Gray ever saw, heard, or read any other communication from Sandoz concerning Parlodel, which he first learned about through his residency.[18] Also absent in the case of Ms. Quinn is any evidence that Dr. Gray relied on the Sandoz information in making his decision to prescribe Parlodel to Ms. Quinn; or any evidence that in the absence of a fraudulent representation or concealment, Dr. Gray would have chosen not to prescribe Parlodel, or would have acted any differently in his treatment of Ms. Quinn. Accordingly, Sandoz's motion for partial summary judgment on Ms. Quinn's fraud claims is due to be granted because the plaintiff has failed to offer any evidence of reasonable reliance.

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and others cited by Sandoz, the issue was whether class certification of fraud and suppression claims would be proper in the absence of evidence that any plaintiff relied on any representations or suppressions made by the defendant. That issue is not sufficiently similar to the case at hand and simply stands for the proposition that reliance, under Alabama fraud law, must be proven in each circumstance and may not be presumed. Id. at 880-81.

[18] To the contrary, Dr. Gray's testimony indicates that he prescribed Parlodel routinely for non-hypertensive, non-allergic patients who chose not to breastfeed, and that his prescribing habits were formed in residency.

5. Damages

The final element the plaintiffs must prove is that the plaintiffs were damaged by the defendant's actions in misrepresenting or concealing the potential hazards of the drug. The fact that each plaintiff was injured is not in dispute. Defendant does, however, dispute that the plaintiffs can show any causative link between the alleged fraud and the injury. This element has been dealt with in detail in this court's Order denying summary judgment on the issue of medical causation, and need not be repeated here. Suffice it to say that both plaintiffs have set forth sufficient evidence of damages to support a cause of action for fraud.

The court finds that, construing the facts in the light most favorable to the plaintiffs as the court must, a reasonable jury could find that Sandoz made misrepresentations to Dr. Gurley, and that Sandoz concealed from Dr. Gurley information about the potential hazards of Parlodel, on which plaintiff Brasher, through Dr. Gurley, relied in taking Parlodel. Accordingly, the defendant's motions for partial summary judgment on the claims of fraud, negligent misrepresentation, and suppression as to Ms. Brasher is due to be denied. As to plaintiff Quinn, the court finds that the plaintiffs have failed to offer any evidence that Ms. Quinn,

through Dr. Gray, relied upon any misrepresentation made by Sandoz. In other words, plaintiff failed to demonstrate that the information provided by Sandoz to Dr. Gray, even if misleading or incomplete, had any effect on Dr. Gray's decision to prescribe Parlodel to Ms. Quinn for PPL. Accordingly, the motion for partial summary judgment on all fraud claims as to Ms. Quinn is due to be granted.

## IV. WARNING CLAIMS

The plaintiffs have asserted claims based on theories that the defendant failed to warn the plaintiffs or their doctors about the hazards of Parlodel. Plaintiff's first claim based on a failure-to-warn theory is set forth as a strict liability claim (Count One). Such a claim is not viable under Alabama law, where the Alabama Supreme Court has specifically retained concepts of negligence in products liability cases and has rejected notions of any no-fault liability. See Griggs v. Combe Inc., 456 So. 2d 790, 792 (Ala. 1984), citing Casrell v. Altec Industries, 335 So. 2d 128, 132 (Ala. 1976), and Atkins v. American Motors Corp., 335 So. 3d 134, 139 (Ala. 1976). Consequently, defendant's motions for partial summary judgment as to Count One are due to be granted.

The plaintiffs have set forth additional warning claims, asserting that Sandoz was negligent in failing to warn of the real risks of Parlodel in postpartum women and that Parlodel is an "unreasonably dangerous" product for which plaintiffs are entitled to relief under the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD").[19] The elements to be proved in a negligence case in Alabama are that the defendant had a duty, breached its duty, and proximately caused harm to the plaintiff. Under the AEMLD, the plaintiff similarly must provide evidence of negligence by showing that the defendant failed to provide adequate warnings of the hazards of Parlodel. See Stone v. Smith, Kline & French Labs., 447 So. 2d 1301, 1303-04 (Ala. 1984).[20] The defendant has moved for partial summary judgment on plaintiffs' failure-to-warn

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[19] The defendant also asserts that plaintiffs' claims for breach of implied and express warranties (Counts Three and Four), and for punitive damages (Count Nine), also are claims based on warning theories. The court, however, finds that those claims, while they may involve questions as to the conduct of Sandoz in developing the warnings, are not governed by a failure-to-warn theory and are not due to be discussed herein. Accordingly, to the extent that the defendant has moved for summary judgment on Counts Three, Four, and Nine, the motion is due to be denied.

[20] The Alabama Supreme Court in Stone noted that Alabama imposes liability for pharmaceuticals companies in the production of prescription drugs pursuant to Comment k to Section 402A of the Restatement (Second) of Torts (1965), which "does no more than codify the principles of negligence." Stone, 447 So. 2d at 1303.

claims on the basis that these are barred by Alabama's learned intermediary doctrine.

It is well settled in Alabama that, in cases involving pharmaceutical companies selling prescription drugs, the learned intermediary doctrine applies. See, e.g., Stone v. Smith, Kline & French Labs., 731 F.2d 1575, 1579-80 (11th Cir. 1984). Under Alabama law, "a manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the use of its product." Toole v. Baxter Healthcare Corp., 235 F.3d 1307 (11th Cir. 2000). The doctrine provides a limited exception to the general rule that the manufacturer must warn the "foreseeable user," (in this case the ultimate consumers, Ms. Quinn and Ms. Brasher), of the hazards posed by its product. Id.

The fact that some warning is given to the doctor, however, is not dispositive of the failure-to-warn issue. Where a warning has been provided, a question arises as to whether the warning was adequate, and adequacy of the warning is a question of fact for the jury. See Toole v. McClintock, 999 F.2d 1430, 1433 (11th Cir. 1993).[21]

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[21] Sandoz argues that summary judgment on the warning claims is due to be granted because the plaintiffs have failed to present expert medical testimony regarding the inadequacy of the

In this case, the plaintiffs assert that the warning provided by Sandoz was inadequate both because it did not fully disclose all the reports of adverse reactions to the drug of which Sandoz was aware, and because the warning failed to acknowledge any causal link between the drug and stroke or other vasocontrictive events, even though Sandoz medical officials had evidence from which it could reasonably conclude that Parlodel could cause such reactions. That knowledge, plaintiffs assert, suggests that Sandoz acted negligently, wantonly, or willfully in failing to adequately warn of the potential hazards of Parlodel.

The defendant counters that the warning set forth in the package insert and in the Dear Doctor letters was approved by the FDA, and that the FDA at all times relevant to this lawsuit approved the use of Parlodel for suppression of postpartum lactation. While those facts are relevant to any evaluation of Sandoz's conduct, they are not dispositive in light of the fact that the plaintiffs argue, and support by admissible evidence, that Sandoz knew of increased risks of the drug and failed or refused to pass that information on to plaintiffs' learned intermediaries, Drs. Gurley and Gray. Viewed in the light most favorable to the

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warning. However, Sandoz fails to cite any authority for such a requirement under Alabama law, and the court finds none.

plaintiffs, Sandoz underreported the number of strokes to the treating physicians through the PDR and failed to send them the "Dear Doctor" letter that might have given them some notice of an increased risk. Under Alabama law, a warning may be deemed inadequate if it "understate[s] the risks" of the drug. Toole, 999 F.2d at 1434.[22]

Under Alabama law, to prevail in a warnings claim, the plaintiffs also must demonstrate a causal link between the allegedly inadequate warning and the injury. In cases such as these, that means that the plaintiffs must demonstrate that, had the defendant given an adequate warning, it would have been read and heeded by the prescribing physicians. See, e.g., Gurley v. American Honda Mtr. Co., 505 So. 2d 358, 361 (Ala. 1987). Dr. Gurley testified that the number of strokes and the statement related to causation included in the PDR were relevant to his assessment of the risk posed by Parlodel. He further testified

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[22] In Toole, the Eleventh Circuit Court of Appeals recognized that, even where a doctor is warned that there is some possibility of an adverse reaction - in that case that a silicone gel breast implant could rupture - that fact does not automatically render the warning adequate. That is because doctors also need to be aware of the frequency of such adverse reactions, because where the reactions may be a "very very unusual event" it poses less of a risk and thus affects the doctor's advice concerning use of the drug or device. Id. at 1433 and n. 6.

that he would not have prescribed Parlodel if Sandoz's warning had included additional information about the incidence of stroke and the causal link between adverse events and Parlodel. Thus, a reasonable jury could determine that Dr. Gurley would not have prescribed Parlodel routinely for Ms. Brasher's postpartum lactation suppression if Sandoz's warning had been adequate. The evidence offered by the plaintiff raises a question of material fact as to the adequacy of Sandoz's warning. Consequently, plaintiff Brasher has presented a *prima facie* case of negligence and a *prima facie* case under the AEMLD, and the defendant's motions for partial summary judgment on the warning claims set forth in Counts Two and Eight are due to be denied as to Ms. Brasher.

The evidence relating to the inadequacy of the warning is lacking, however, with respect to the claims set forth by plaintiff Quinn. There is simply no evidence offered by Ms. Quinn that, had Sandoz given a more adequate warning, Dr. Gray would have read and heeded the warning. In fact, there is no evidence that any communication by Sandoz would have influenced Dr. Gray's decision to prescribe Parlodel to Ms. Quinn.[23]

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[23] It is true that when read in context, Dr. Gray's deposition suggests that had other prescribing OB/GYN doctors at Brookwood Hospital taken Parlodel off the standing orders - presumably on the basis of a strengthened warning by Sandoz, he, too, would have stopped prescribing Parlodel for PPL and

## V. CONCLUSION

The court finds that plaintiff Elizabeth Brasher has shown there to be triable issues of fraud, suppression, and negligent misrepresentation under the AEMLD. The defendant's motion for partial summary judgment on these claims (Brasher documents # 63, 127) is therefore due to be denied. The court finds that plaintiff Ruby Quinn has failed to show that there are triable issues as to her claims of fraud, suppression, and negligent misrepresentation. Accordingly, defendant's motion for partial summary judgment on the fraud claims (Quinn documents # 56, 113) is due to be granted. Similarly, Ms. Brasher has demonstrated that there exist genuine issues of material fact as to the adequacy of the warnings given to plaintiff through her physician, and therefore the defendant's motion for partial summary judgment on the warning claims (Brasher document #66) is due to be denied. Ms. Quinn has failed to demonstrate the inadequacy of the warning,

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therefore would not have prescribed Parlodel to Ms. Quinn. This conclusion, however, is too tenuous to refute the defendant's evidence in support of its motion for summary judgment, and is simply insufficient to salvage plaintiff's claims. To allow plaintiff's claims to survive on such an "assumption" would be to essentially let plaintiffs pursue a fraud-on-the-FDA or fraud-on-the-market claim, which is not permissible in light of Buckman, as discussed *supra*.

however, and defendant's motion for partial summary judgment as to her warning claims (Quinn document #57) is due to be granted.

Both plaintiffs have failed to demonstrate that there is any genuine issue of material fact as to their claims based on fraud-on-the-FDA and on strict liability, however, and the motions with respect to those claims (Brasher document # 127, Quinn document #113) are thus due to be granted.

A separate order denying in part and granting in part the defendant's motions for partial summary judgment will be entered contemporaneously herewith.

DONE this the 21st day of September, 2001.

T. MICHAEL PUTNAM
CHIEF MAGISTRATE JUDGE